

**Application No.: 10/652,100**  
**Filing Date: August 28, 2003**

## **REMARKS**

The foregoing amendments and the following remarks are responsive to the November 13, 2008 Office Action (the “Office Action”).

### *Claim Rejections:*

While Applicant respectfully disagrees with the Examiner’s rejections, to advance prosecution, Applicant has amended one or more claims to address the Examiner’s comments. Applicant is not acquiescing to the rejections and reserves the right to pursue in a related application claims at least as broad as the amended claims prior to the amendments set forth herein. Applicant respectfully requests the Examiner to reconsider the above-captioned application in view of the foregoing amendments and the following comments.

### *Amendments to the Specification:*

The specification has been amended herein to correct for spelling and terminology errors. Applicant submits that no new matter is being introduced by the amendments to the specification.

### *Prosecution History:*

In Applicant’s reply dated July 27, 2007, Applicant, *inter alia*, elected with traverse Claims 1-31 for further prosecution. By this present Amendment, new dependent Claim 69-70 are added, the new claims being directed to Group I that was elected on July 27, 2007. Applicant submits that no new matter is being introduced by this amendment, and that Claims 69-70 are allowable for at least the same reasons as for the claim or claims from which they depend (as described below) and also because they each recite further patentable distinctions.

Additionally, Applicant notes that previously withdrawn independent Claims 32, 35, and 38 have been amended so that they are now in dependent form, depending from pending, elected claims. These claims are still withdrawn from consideration. Similarly, previously withdrawn dependent Claims 33, 36, and 39 have been amended in a manner that is consistent with the amendments to Claims 32, 35, and 38. Applicant respectfully reserves the right to reinstate these claims after the elected claims from which they depend are allowed.

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Claim Rejections – 35 U.S.C. 102 – Claims 1-2, 5, 53-57, 59, and 63-65:

The Examiner rejected Claims 1-2, 5, 53-57, 59, and 63-65 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application No. 2003/0108587 (“Orgill”). Respectfully stated, none of Claims 1-2, 5, 53-57, 59, and 63-65 is anticipated by Orgill under 35 U.S.C. 102(e) because Orgill does not show every element of each claim arranged as in each claim. *See* MPEP §2131. Moreover, as discussed below, Orgill also does not render obvious any of these claims.

Independent Claims 1, 5 and 53:

Applicant has amended Claims 1, 5, and 53 as discussed during the February 19, 2009 interview (the “Interview”) to clarify the distinctions between the inventions set forth in Claims 1, 5, and 53 and the apparatuses disclosed in Orgill.

In particular, Applicant has amended Claims 1, 5, and 53 to clarify that the first material of the absorbable matrix is different than the second material of the absorbable matrix. As discussed during the Interview, Applicant submits that amended Claims 1, 5, and 53 are not disclosed or suggested by Orgill, and would not be obvious in view of Orgill.

Applicants further submit that dependent Claims 2, 54-57, 59, and 63-65 are not anticipated by, suggested by, or obvious in view of Orgill for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions. In particular, Claims 63-64 were rejected under 35 U.S.C. 102(e) as being anticipated by Orgill. While this may have been a typographical error in the Office Action, Applicants wish to address the rejection of these claims to ensure that this Amendment is completely responsive to the Office Action.

The rejection does not state that Orgill anticipates the invention of Claim 24 (from which Claims 63-64 depend), much less *how or why* Orgill anticipates the invention of Claim 24. Applicants submit that Orgill does not disclose or suggest the limitations set forth in Claim 24 for at least the following reasons.

In particular, Claim 24 was amended in Applicant’s August 1, 2008 response to distinctly point out that, *inter alia*, unlike the apparatus disclosed in Orgill, the temperature monitor of Claim 24 is positioned within the periphery of the cover. Applicant submits that Orgill does not disclose or suggest an appliance comprising a cover and a temperature monitor supported by the

cover and positioned within a periphery of the cover, wherein the temperature monitor is configured to provide a visual indication of the temperature of the wound such that a visual inspection of the appearance of the temperature monitor provides an indication of the temperature of the wound. There are at least two distinct differences between the appliance set forth in Claim 24 and Orgill's embodiment described at paragraph 94 and illustrated in Figure 10A.

First, Orgill does not disclose or suggest that the wound sensor array 170 (which the Office Action compares to the temperature monitor of Claim 24) itself provides a visual indication of the temperature of the wound such that a visual inspection of the appearance of the wound sensor array 170 provides an indication of the temperature of the wound. Rather, as set forth in paragraph 94, the "sensor probes 175 are entrained in the matrix 105 and fed through the occlusive dressing 115 to a sensor output 180." Importantly, "[t]his sensor output 180 provides valuable information about the wound microenvironment ..." (underlining added). This disclosure makes it indisputably clear that Orgill's sensor array 170 does not itself provide a visual indication of the temperature of the wound such that a visual inspection of the appearance of the [sensor array 170] provide an indication of the temperature of the wound, as set forth in Claim 1. Second, the wound sensor array in Orgill is placed in the wound itself, and is not supported by Orgill's dressing 115.

Additionally, Applicant submits that Claims 63-64 are not anticipated or suggested by Orgill for at least the same reasons as for Claim 24 from which Claims 63 and 64 depend, and also because Claims 63 and 64 each recite further patentable distinctions. In particular, regarding Claim 64, for the same reasons as discussed above with respect to Claim 24, Orgill does not disclose a wound cover having, inter alia, a temperature monitor integral with the cover. In particular, respectfully stated, Orgill's feature 180 is not a temperature-sensitive material as stated in the Office Action. Rather, as described in paragraph 94, feature 180 is a "sensor output" that is, pursuant to every reasonable interpretation of paragraph 94 and Figure 10A, located outside of the wound bed. This conclusion is made inescapable by Orgill's statement in paragraph 94 that the "sensor probes 175 are ... fed through the occlusive dressing 115 to a sensor output 180." (underlining added). Therefore, neither Orgill's sensor probes 175 nor Orgill's sensor output 180 are disclosed or suggested as being integral with Orgill's occlusive dressing 115.

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Accordingly, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 1-2, 5, 53-57, 59, and 63-65 in view of the amendments and clarifications listed above and to pass these claims to allowance.

*Claim Rejections – 35 U.S.C. 102 - Claims 6, 8-11, 14, 16-21, 61-62, and 66-67:*

The Examiner rejected Claims 6, 8-11, 14, 16-21, 61-62, and 66-67 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Application No. 2003/0050594 (“Zamierowski”). Respectfully stated, Claims 6, 8-11, 14, and 16-21 are not anticipated by Zamierowski under 35 U.S.C. 102(e) because Zamierowski does not show every element of each claim arranged as in each claim. *See* MPEP §2131. Moreover, as discussed below Zamierowski also does not render obvious any of these claims.

*Independent Claim 6:*

Applicant has amended Claim 6 as proposed during the Interview to clarify the distinctions between the inventions set forth in Claim 6 and the systems disclosed in Zamierowski. In particular, Claim 6 has been amended to clarify that each of the plurality of protrusions is spaced apart from the other protrusions about an outside surface of the cover.

Regarding Applicant’s amended Claim 6, as discussed during the interview, Zamierowski does not disclose or suggest, *inter alia*, an appliance for monitoring pressure during treatment of any body part of a patient comprising a cover having, *inter alia*, a plurality of protrusions configured to monitor the level of the pressure at the site of the body part being treated, wherein each of the protrusions are spaced apart from the other protrusions about an outside surface of the cover.

By contrast, Zamierowski’s paragraph 54 and Figure 5a describe a “bellows-type tubing section 110a.” The bellows-type tubing section 110a is never disclosed or suggested by Zamierowski as being configured to monitor the level of pressure under Zamierowski’s wound dressing 102, nor does Zamierowski disclose a plurality of protrusions spaced apart from the other protrusions about an outside surface of the cover.

Paragraph 59 states that, [i]n operation, evacuating the dressing 202 causes portions of it to shrink, compress and collapse under the pressure gradient, thus providing a visual indication

of its performance." There are at least three points of distinction between this description set forth in paragraph 59 and the invention set forth in Claim 6.

- First, Zamierowski's paragraph 59 does not disclose or suggest that Zamierowski's dressing 202 comprises a plurality of protrusions, each of which is spaced apart from the other protrusions about an outside surface of the cover, as in amended Claim 6.

- Further, Zamierowski does not disclose or suggest in paragraph 59 or otherwise that the dressing 202 (of Figure 8, as described in Zamierowski's paragraph 59) monitors the level of pressure at the site of the body part being treated. Paragraph 59 merely discloses that the performance (to be distinguished from the level of pressure) of the dressing 202 can be visually indicated.

- Finally, Applicant's Claim 6 states that the protrusions are configured to monitor the level of pressure, whereas Zamierowski's paragraph 59 states that the dressing 202 (as opposed to some other feature supported by the dressing) provides a visual indication of the dressing's performance.

Independent Claim 14:

Applicant has amended Claim 14 as proposed during the Interview to clarify the distinctions between the invention set forth in Claim 14 and the systems disclosed in Zamierowski. In particular, Claim 14 has been amended to clarify that the appliance comprises a conduit configured to supply a source of reduced pressure to the space between the cover and the wound, and to clarify that the pressure monitor is supported by the cover separate from the conduit.

Regarding Applicant's amended Claim 14, as discussed during the interview, Zamierowski does not disclose or suggest, inter alia, an appliance for administering a reduced pressure treatment to a wound, comprising, inter alia, a pressure monitor supported by the cover and separate from the conduit, the pressure monitor being configured to provide a visual indication of the level of reduced pressure between the cover and the wound such that a visual inspection of the appearance of the pressure monitor provides an indication of the level of reduced pressure between the cover and the wound.

By contrast, Zamierowski's paragraph 54 and Figure 5a describe a "bellows-type tubing section 110a." The bellows-type tubing section 110a is never disclosed or suggested by

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Zamierowski as being configured to provide a visual indication of the level of reduced pressure between the cover and the wound such that a visual inspection of the appearance of the pressure monitor provides an indication of the level of reduced pressure between the cover and the wound, as set forth in Claim 14. Nor does Zamierowski disclose that a pressure monitor supported by the cover and separate from the conduit.

As with Claim 6, there are at least three points of distinction between this description set forth in paragraph 59 and the invention set forth in Claim 14.

- First, Zamierowski's paragraph 59 does not disclose or suggest that the dressing 202 comprises a pressure monitor supported by the cover and separate from the conduit, as in amended Claim 14.

- Further, Zamierowski does not disclose or suggest in paragraph 59 or otherwise that the dressing 202 (of Figure 8, as described in Zamierowski's paragraph 59) is configured to provide a visual indication of the level of reduced pressure between the cover and the wound. Paragraph 59 merely discloses that the performance (to be distinguished from the level of pressure) of the dressing 202 can be visually indicated.

- Finally, Applicant's Claim 14 states that the pressure monitor supported by the cover is configured to provide a visual indication of the level of reduced pressure between the cover and the wound, whereas Zamierowski's paragraph 59 states that the dressing 202 (as opposed to some other feature supported by the dressing) provides a visual indication of the dressing's performance.

Claims 8-11, 16-21, 61-62, and 66-67:

Regarding Claims 8-11, 16-21, 61-62, and 66-67, respectfully stated, these claims are not anticipated or suggested by Zamierowski for at least the same reasons as for the claim or claims from which they depend, and also because they each recite further patentable distinctions. In particular, regarding Claim 17, Zamierowski's paragraph 53 states that the feature 106 is a collector assembly. Zamierowski does not disclose or suggest the appliance of Claim 14, further comprising an absorbable matrix adapted to encourage growth of tissue in the area of the wound into the matrix. Accordingly, Applicant respectfully requests that Examiner reconsider and withdraw the rejection of Claims 6, 8-11, 14, 16-21, and 61-62 in view of the amendments and clarifications listed above.

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Therefore, Applicant respectfully requests the Examiner to reconsider and withdraw the rejection of Claims 6, 8-11, 14, 16-21, 61-62, and 66-67 in view of the amendments and clarifications listed above and to pass these claims to allowance.

Claim Rejections – 35 U.S.C. 103:

Claims 3 and 25:

The Examiner rejected Claims 3 and 25 under 35 U.S.C. 103(a) as being unpatentable over Orgill in view of U.S. Patent Application Publication No. 2002/0065494 (“Lockwood”). Respectfully stated, Claims 3 and 25 are not unpatentable over Orgill in view of Lockwood because Lockwood does not overcome Orgill’s failure to disclose or suggest all of the limitations set forth in the claims from which Claims 3 and 25 depend (described above), and because the additional patentable limitations set forth in Claims 3 and 25 and the limitations of the claims from which they depend would not have been obvious to one of ordinary skill in the art in view of Orgill and Lockwood at the time of the inventions.

Claims 24-29, 60, 64, and 68:

The Examiner rejected Claims 24-29, 60, 64, and 68 under 35 U.S.C. 103(a) as being unpatentable over Orgill in view of U.S. Patent Application No. 2003/0014025 (“Allen”).

Amended Claim 24 sets forth an appliance for administering a reduced pressure treatment to a wound, comprising a cover having a periphery adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound; and a temperature monitor supported by the cover and positioned within the periphery of the cover; wherein the temperature monitor is configured to change color when the temperature of the wound falls below normal body temperature so as to provide a visual indication of the temperature of the wound below normal body temperature such that a visual inspection of the appearance of the temperature monitor provides an indication of the temperature of the wound.

In particular, Applicant submits that Orgill in view of Allen does not disclose, suggest, or render obvious Claim 24 because Orgill in view of Allen does not disclose, suggest, or render obvious an appliance comprising, inter alia, a temperature monitor configured to change color when the temperature of the wound falls below normal body temperature so as to provide a visual indication of the temperature of the wound below normal body temperature.

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In contrast, Allen is directed to an “Absorbent Article Having A Fever Indicator,” as indicated by the title of Allen. (underlining added). *See also*, ¶ 13 (“[t]he present invention is directed to a fever indicator . . .”) (underlining added); ¶ 20 (“[t]he article of the present invention further comprises a fever indicator 60 that provides a . . . signal of an elevated core body temperature of the wearer of the article.”) (underlining added); ¶ 21 (“. . . the fever indicator 60 may provide a qualitative visual indication that the urine temperature, and therefore the core body temperature, is above a pre-defined threshold value.”) (underlining added); ¶ 21 (“[t]herefore, the fever indicator 60 may be designed . . . to indicate . . . that the temperature of the urine is at about 101 degrees F . . . or above.”) (underlining added). Accordingly, Applicant submits that Allen does not disclose or suggest an absorbent article for non-elevated or fever related temperatures.

Additionally, as addressed in previous Office Action responses, Applicant maintains its position that there would be no reasonable expectation of success in combining Orgill and Allen. In particular, Applicant submits that Allen is not analogous prior art and therefore cannot be combined with Orgill in any manner for a rejection under 35 U.S.C. 103. Please see Applicant’s Amendment filed on August 1, 2008, for a more detailed discussion of this argument.

Claims 30 and 31:

The Examiner rejected Claims 30 and 31 under 35 U.S.C. 103(a) as being unpatentable over Orgill in view of U.S. Patent No. 7,004,915 (“Boynton”). Respectfully stated, Claims 30 and 31 are not unpatentable over Orgill in view of Boynton because Boynton does not overcome Orgill’s failure to disclose or suggest all of the limitations set forth in the claims from which Claims 30 and 31 depend (described above), and because the additional patentable limitations set forth in Claims 30 and 31 and the limitations of the claims from which they depend would not have been obvious to one of ordinary skill in the art in view of Orgill and Boynton at the time of the inventions. In particular, regarding Claim 30, on Applicant’s understanding, Boynton discloses an alarm that may be automatically activated if an air leak is detected at the wound site (see column 7, lines 30-31). However, neither Orgill nor Boynton disclose or suggest an alarm device that provides an alarm signal when the *temperature* measured by any temperature sensing device exceeds or is lower than a predetermined value.

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Claim 58:

The Examiner rejected Claim 58 under 35 U.S.C. 103(a) as being unpatentable over Orgill in view of U.S. Patent No. 7,070,584 ("Johnson"). Respectfully stated, Claim 58 is not unpatentable over Orgill in view of Johnson because Johnson does not overcome Orgill's failure to disclose or suggest all of the limitations set forth in Claim 1 from which Claim 58 depends (described above), and because the additional patentable limitations set forth in Claim 58 and the limitations of Claim 1 would not have been obvious to one of ordinary skill in the art in view of Orgill and Johnson at the time of the inventions.

In particular, Johnson does not disclose or suggest an absorbable matrix comprising a first absorbable portion formed from a first material having a first rate of absorption of tissue into the first absorbable portion and a second absorbable portion formed from a second material having a second rate of absorption of tissue into the second absorbable portion, wherein the first rate of absorption is different than the second rate of absorption. Further, regarding the limitations set forth in Claim 58, Johnson's claim 11 specifically states that "third pad [is] comprised of a non-bioabsorbable substrate removable [sic] coupled to the second pad." (underlining added). Therefore, Johnson does not disclose or suggest, or rendered obvious, inter alia, the third absorbable portion of Claim 58 formed from a third material having a third rate of absorption of tissue into the third absorbable portion.

Claims 7, 12-13, 15, and 22-23:

The Examiner rejected Claims 7, 12-13, 15, and 22-23 under 35 U.S.C. 103(a) as being unpatentable over Zamierowski in view of Lockwood. Respectfully stated, Claims 7, 12-13, 15, and 22-23 are not unpatentable over Zamierowski in view of Lockwood because Lockwood does not overcome Zamierowski's failure to disclose or suggest all of the limitations set forth in the claims from which Claims 7, 12-13, 15, and 22-23 depend (described above), and because the additional patentable limitations set forth in Claims 7, 12-13, 15, and 22-23 and the limitations of the claims from they depend would not have been obvious to one of ordinary skill in the art in view of Zamierowski and Lockwood at the time of the inventions.

No Disclaimers or Disavowals:

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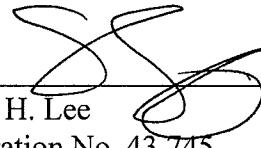
Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 3-13-09

By:   
Sabing H. Lee  
Registration No. 43,745  
Attorney of Record  
Customer No. 20995  
(949) 760-0404

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